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### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF

JARAI ET AL.

APPLICATION NO: Not Yet Assigned,

Continuation of 09/575,302

FILED: MAY 19, 2000 FOR: NOVEL GENE

Assistant Commissioner for Patents Washington, D.C. 20231

### PRELIMINARY AMENDMENT

Sir:

Prior to examination on the merits, please amend the above-identified application as follows.

## **IN THE SPECIFICATION:**

Please insert pages 1 to 4 of the Sequence Listing submitted herewith after the abstract.

## IN THE CLAIMS:

Please cancel claims 3, 4, 5, 8, 10 and 12 to 16.

Please enter the following claims, replacing the previous claims with the same numbers.

Please add new claims 17 to 19.

### **CLEAN COPY OF THE CLAIMS**

- 1. (Amended) An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2.
- 2. (Amended) An isolated polynucleotide according to claim 1 which is cDNA comprising the nucleotide sequence of SEQ ID NO:1, or a DNA comprising a nucleotide sequence which hybridizes to SEQ ID NO:1 under conditions which allow up to 20% base pair mismatches, said conditions comprising two 15 minute washes in a solution consisting of 15mM NaCl, 1.5 mM sodium citrate, pH 7.0 at 65°C.
- 6. A method of producing a polypeptide which comprises culturing a host cell containing an expression vector containing a polynucleotide sequence as specified in claim 1, under conditions suitable for expression of the polypeptide and recovering the polypeptide from the host cell culture.
- 7. An expression vector containing a polynucleotide sequence as specified in claim 1.
- 9. (Amended) An antisense oligonucleotide comprising a nucleotide sequence complementary to that of a polynucleotide encoding a polypeptide comprising SEQ ID NO:2.
- 11. (Amended) A composition comprising a polynucleotide according to claim 1, a polypeptide comprising the amino acid sequence of SEQ ID NO:2 [or a functionally equivalent variant thereof], an antibody which is immunoreactive with said polypeptide or an antisense oligonucleotide comprising a nucleotide sequence complementary to that of said polynucleotide, optionally further comprising a pharmaceutically acceptable carrier.
- 17. (New) A polymerase chain reaction primer consisting of between 15 and 24 nucleotides, wherein the sequence of said nucleotides is identical to or complementary to an identical number of contiguous nucleotides of the isolated polynucleotide of claim 1.
- 18. (New) A method for diagnosing an inflammatory disease associated with increased GM-CSF production in a subject comprising:

assaying tissue from a subject for a member selected from the group consisting of increased transcription of a polynucleotide according to claim 1 and increased expression of a polypeptide comprising SEQ ID NO:2,

wherein detection of increased transcription of a polynucleotide according to claim 1 or detection of increased expression of a polypeptide comprising SEQ ID NO:2 indicates that the subject is suffering from an inflammatory disease associated with increased GM-CSF production.

19. (New) The method of claim 18, wherein said inflammatory disease associated with increased GM-CSF production is selected from the group consisting of acute bronchitis, chronic bronchitis, chronic obstructive pulmonary disease, emphysema, asthma, and adult respiratory distress syndrome, rheumatoid arthritis, inflammatory bowel disease, ulcerative colitis, primary sclerosing cholangitis, and Crohn's disease.

### REMARKS

By this preliminary amendment, claims 3 to 5, 8, 10, and 12 to 16 have been canceled. Claims 1, 2, 9, and 11 have been amended. New claims 17 to 19 have been added. Thus, claims 1, 2, 6, 7, 9, 11, and 17 to 19 are pending and are at issue.

Claim 1 has been amended by the deletion of the term "or a functionally equivalent variant of said amino acid sequence." Claim 2 has been amended to change the spelling of "hybridises" to "hybridizes" and to add the specific conditions which comprise stringent hybridization conditions. This amendment is supported at, *inter alia*, page 4, second paragraph of the specification. Claim 9 has been amended to recite SEQ ID NO:2 in order to eliminate the dependency on canceled claim 4. Claim 11 has been amended to change the non-standard "optionally together" language to "further comprising" in order to more clearly point out that which is claimed. The amendment is a matter of word choice, and does not affect the scope of the claim.

New claim 17 is directed to polynucleotides useful as PCR primers. Support for new claim 17 can be found, *inter alia*, in original claim 16 and in the Sequence Listing, especially SEQ ID NOs. 3 to 6. New claims 18 and 19 are directed to methods of diagnosis of inflammatory diseases utilizing the polynucleotides and polypeptides of the invention, and finds support, *inter alia*, at page 1, fourth paragraph, and page 8, third paragraph of the specification, which specifically recite diagnostic uses for the nucleotides and polypeptides of the invention.

Thus, no new matter has been added by the amendments to the claims.

An early and favorable action on the merits is respectfully requested.

Respectfully submitted,

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Date: October 26, 2001

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# MARKED UP COPY OF AMENDED CLAIMS

- 1. (Amended) An isolated polynucleotide comprising a nucleotide sequence encoding a polypeptide comprising the amino acid sequence of SEQ ID NO:2 [or a functionally equivalent variant of said amino acid sequence].
- 2. (Amended) An isolated polynucleotide according to claim 1 which is cDNA comprising the nucleotide sequence of SEQ ID NO:1, or a DNA comprising a nucleotide sequence which [hybridises] <a href="https://doi.org/10.20%/base-pair-mismatches">hybridises</a>] <a href="https://doi.org/10.20%/base-pair-mismatches">hybridises</a>] <a href="https://doi.org/10.20%/base-pair-mismatches">hybridises</a>] <a href="https://doi.org/10.20%/base-pair-mismatches">hybridises</a>] <a href="https://doi.org/10.20%/base-pair-mismatches">hybridises</a>] <a href="https://doi.org/10.20%/base-pair-mismatches">hybridises</a>] <a href="https://doi.org/10.20%/base-pair-mismatches-comprising-two-15 minute-washes-in-a solution consisting-of-15mM NaCl, 1.5 mM-sodium-citrate, pH 7.0 at 65°C.
- 9. (Amended) An antisense oligonucleotide comprising a nucleotide sequence complementary to that of a polynucleotide encoding a polypeptide [according to claim 4] <u>comprising SEQ ID NO:2</u>.
- 11. (Amended) A [pharmaceutical] composition comprising a polynucleotide according to claim 1, a polypeptide comprising the amino acid sequence of SEQ ID NO:2 [or a functionally equivalent variant thereof], an antibody which is immunoreactive with said polypeptide or an antisense oligonucleotide comprising a nucleotide sequence complementary to that of said polynucleotide, optionally [together with] <u>further comprising</u> a pharmaceutically acceptable carrier.